JUL 2 6 2002

K022164

510(k) Summary

Zeta Development Laboratories

Name of device: Zeta Diagnostic Retinal Imaging System

Common or usual name: Camera, Ophthalmic (AC Powered)

Classification Name: Ophthalmic Camera (per 21 CFR.886.1120)

Product Code: HKI

Submitter: Zeta Development Laboratories
4990 Hillsdale Circle, Suite 400
El Dorado Hills, CA 95762
Phone: (916) 941-0800
Facsimile: (916) 941-8345
Contact Person: Mark T. Fukuhara
Date Prepared: 20 May 2002

Predicate Devices

Trade Name	Manufacturer	510 (k)
WinStation Retinal Imager	Ophthalmic Imaging Systems	K982689
Ophthavision Imaging System	MRP Group, Inc.	K980295
ImageScope Digital Imaging System	Tomey Corporation USA	K971685
Imagenet Digital Ophthalmic Imaging	Topcon	K870039

Intended Use

The Zeta Diagnostic Retinal Imaging System is intended to be used to capture, archive, and display digital images of the eye, particularly the retina obtained through the use of an ophthalmic camera (fundus camera). The Zeta System is an automated imaging device used in conjunction with a fundus camera that

requires minimal intervention during the capture of an image. The system is simple to use and requires minimal training for a user to become proficient with the system. Like the listed predicate devices, the Zeta System is comprised of a digital imaging camera or cameras, computer hardware, and a software platform intended to be used to store images captured by the fundus camera. Thus the Zeta Diagnostic Retinal Imaging System has the same intended use and indications as the listed predicate devices.

Substantial Equivalence

The Zeta Diagnostic Retinal Imaging System and the predicate devices listed all have the same intended use: to capture and archive images of the retina taken with a fundus camera. The Zeta Diagnostic Retinal Imaging System and the predicate devices listed have similar or the same principles of operation and technological characteristics. Each of the devices is a digital ophthalmic camera system. The user views the patient's retina through a fundus camera. A light source is used to illuminate the retina and the fundus triggers the digital cameras to capture images of the retina. These digitized images are then archived for future use or record.

The Zeta Diagnostic Retinal Imaging System, the Ophthalmic Imaging Systems WinStation Digital Imaging System, and the MRP Group's OphthaVision system have significantly similar technological characteristics including the exact same digital cameras used to capture images taken by a fundus camera.

The Zeta Diagnostic Retinal Imaging System and all of the listed predicate devices use, and are operated by, PC's with keyboards and a hand operated mouse. While there may be some very minor differences in types of processor (Intel Pentium III or IV or AMD Athelon) processors speed, and software platform, these minor differences do not raise any new issues of safety or effectiveness and do not affect the imaging capabilities of the Zeta Device or any of the predicate devices listed.

The Zeta Diagnostic Retinal Imaging System and all of the predicate devices have the same basic software functions: image acquisition, storage, analysis, and retrieval. The principle differences can be found in the graphical user interface.

Most software platforms found in the predicate devices are windows based and effectively function using different screens for different functions, and drop down menus and graphic buttons to control, or perform, various tasks in the capture, archive, and recall of images.
These slight differences do not raise new or additional questions regarding safety or efficacy in the Zeta or other predicate systems. Zeta Development Laboratories has performed several software validation tests the results of which clearly indicate that the Zeta device meets comparable system and software standards exhibited by the predicate devices listed.

The Zeta system and all of the predicate devices listed are operated in the same manner. The Ophthalmologist, or Photographer, views the patients eye through an ophthalmic camera (fundus camera) with a digital camera mounted on this ophthalmic camera to capture, manipulate and archive images using the graphical user software interface. The Zeta system and all of the predicate devices listed use the system software to manipulate images into produce proof sheets (photo collages of the patients eye captured during the procedure) the software also carries the capabilities of printing individual images or proof sheets, view individual photos or proof sheets on the computer monitor, and to archive selected captured images onto the computers hard drive or several types of removable media such as Magnetic Tape, Jazz discs or standard CD's.

Performance characteristics

The Zeta Diagnostic Retinal Imaging System is comprised of the following components: A digital sensor head (digital camera) a computer interface circuit board (digital image capture card), and connecting cables. These components are then combined and sold together with our "eyepix" proprietary imaging software and a computer (CPU) monitor, keyboard and mouse. This total system with imaging software provides acquisition and hardware control capabilities used in conjunction with a fundus camera to take digital pictures of the retina which are then transferred via the digital camera and connecting cable to the computer system where they can be viewed, modified, stored or printed. The Zeta system is intended to capture and store images of the fundus, and it is also indicated for use as an ophthalmic camera for individuals where examination of the fundus have been requested for pathologies.

The Zeta Diagnostic Retinal Imaging System user software interface allows images from the fundus camera to be acquired, monitored, stored and retrieved. Imaging focusing and camera orientation in relation to the retina are controlled by the user. With verification and monitoring by the user, the software allows the user to monitor, capture, and process, verifying the device is operating correctly. The image viewed through the fundus camera and acquired by Zeta's system is then stored as individual images in a non compressed state on the hard drive of the computer to be displayed electronically as the user requires it.

Conclusion

The Zeta Development Laboratories Retinal Imaging System has the same intended use, indications, and very similar principals of operation to the predicate devices listed. The Zeta System has similar technological characteristics (hardware and software) to the Tomey and Topcon systems and exactly the same technical characteristics as the Ophthalmic Imaging Systems and MRP Group, Inc.'s Products. **The minor differences between the Zeta product and those of the listed predicate devices do not raise any new questions of safety or the effectiveness of the Zeta system in comparison to the predicate devices. Thus the Zeta Development Laboratories Diagnostic Retinal Imaging System is substantially equivalent to legally marketed ophthalmic camera systems.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 6 2002

Zeta Development Laboratories
c/o Mr. Michael Kwan
1655 Scott Blvd.
Santa Clara, Ca 95050

Re: K022164
Trade/Device Name: Zeta Diagnostic Retinal Imaging System
Regulation Number: 868.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: July 23, 2002
Received: July 24, 2002

Dear Mr. Kwan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Statement of Indications for Use

510(k) Number (if Known): K022164

Device Name: Zeta Diagnostic Retinal Imaging System

Indications for Use :

The Zeta Diagnostic Retinal Imaging System is intended to be used to capture, archive, recall and display black and white, and color images of the retina captured using an ophthalmic camera during angiography non-invasively.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K022164

Prescription Use ✓ or Over-the-counter Use _____
(Per CFR 21 801.109)